Efficacy of Calcium and Vitamin D Supplementation in Female Navy Recruits for the Reduction of Stress Fracture

- Principal Investigator: ***J. M. Lappe(Creighton)***
- Co-Investigators: ***R.L. Ahlf (NIDBR)***

  D. Cullen (Creighton)

  K. Thompson (NHRC)
- Key Support Personnel: ***V.G. Morales (NIDBR)***

  D.L. Berry (NIDBR)

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Stress Fracture

Most frequent injury occurring during basic trai
The U.S. military

Stress Fracture

- *Occurs when bones are repetitively loaded o periods without sufficient time for repair.*
- *Due to fatigue failure that develops when ea cycle produces a minute amount of microda accumulates with repetitive loading.*
- *Occurs most often among persons with norm and no acute injury who are involved in phys activity to which they are not adapted.*

- Einhorn, 1996

Risk Factors for Stress Fracture

Genetic

Female gender

Race (White, Hispanic or Asian)

Short height

Low bone density or poor bone structure

Lifestyle

Amenorrhea

Smoking, alcohol consump

Low calcium intake

Fitness

Previous injury

Low fitness or activity before enlistment

Poor muscle strength

Risk Factors Risk Prediction

- ✓ *Predictor variables have been poor specificity*
- ✓ *Difficult to target recruits who might benefit from less rigorous training programs*
- ✓ *Since alternate programs add cost to training, the military services are reluctant to implement such programs unless they can be highly targeted.*

Training Changes Implemented at Great Lakes

Shortened stride length

-shorter persons in front of group

Decreased

-time running boots

-double-time

-transit mileage

-standing time

Specific Aims of the Study

1. *To determine if calcium and vitamin D intervention can reduce stress fracture incidence in female Naval Recruits during basic training.*
2. *To examine potential mechanisms for increasing bone adaptation to intense mechanical loading.*

Rationale for Calcium and Vitamin D Supplementation in Naval Recruits

- **Calcium Balance is Compromised**
  - *Ca deficient diet upon entry in BT.*

    Minimum recommended Ca 1000mg/d

    Average Ca intake 19 – 30 yrs 600-700mg/d

    Median Ca intake of women during BT 700-900mg/d
  - *High Ca losses occur in sweat during strenuous activity. (Study with collegiate basketball players*

    Klesges, et al. 1996)

Rationale for Calcium and Vitamin D Supplementation in Naval Recruits

- **Calcium Balance is Compromised**
  - *Recruits below age 30 have not achieved peak bone mass and require a positive Ca balance for bone gain. (maximize peak bone mass).*
  - *Intense training stimulates bone formation, increasing Ca demands. (maximize bone adaptation)*
  - *Microfracture repair is dependent upon Ca availability. (maximize repair process)*

Hypothesis

Female naval recruits given calcium supplementation of 2000 mg/d and Vitamin D supplementation of 800 I.U. compared to recruits given placebo tablets will have a lower incidence of stress fracture during eight weeks of basic training.

Experimental Design

- **Randomized, Double Blind, Placebo Controlled**
  - *Treatment groups*

    1. Active 2000 mg Ca and 800 I.U. of Vit D

    (Oscal plus D)

    2. Placebo

  Subjects are given two tablets with breakfast and

  two with dinner

Measurements

1. *Ascertainment of stress fractures during BT. Confirmed with radiography or technetium scan according to usual Navy protocol.*
2. *Questionnaire to determine risk factors for fracture.*
3. *Self-report of menstrual cycle regularity during BT.*
4. *Tibial pQCT measured at the beginning and end of BT in a subset of study participants.*

XCT 3000 (Stratec-Medizintechn

Procedure

Female Recruits are approached during Day 1 of processing

- *written informed consent*
- *risk factor questionnaire*
- *random assignment to Ca/Vit D or placebo supplements (red or blue dog tag silencers)*
- *calendar for recording menstrual flow*
- *pQCT*

Procedure

Supplements are picked up by recruits in the galley at meals. They are in small bags with red or blue lines to indicate the treatment assignment.

Procedure

Study monitoring

-Visit recruits in their compartments

-Check mess halls during meals

-Collect menstrual calendars and brief exit interview

Applicability of Findings

- ***The levels of calcium and vitamin D supplementation are very safe.***
- ***Cost of supplement pills is low.***
- ***Many foods are fortified with calcium.***

Thus, positive findings from this study would provide a realistic method of decreasing stress fracture incidence.

Progress of Study to Date

Data collection started in May 2002

All clinical studies at Great Lakes (GL) halted in October 2002

Study restarted in September 2003

pQCT amendment submitted to GL IRB in September 2003

pQCT approved by GL, submitted to DOD in January 2004 and approved in May 2004

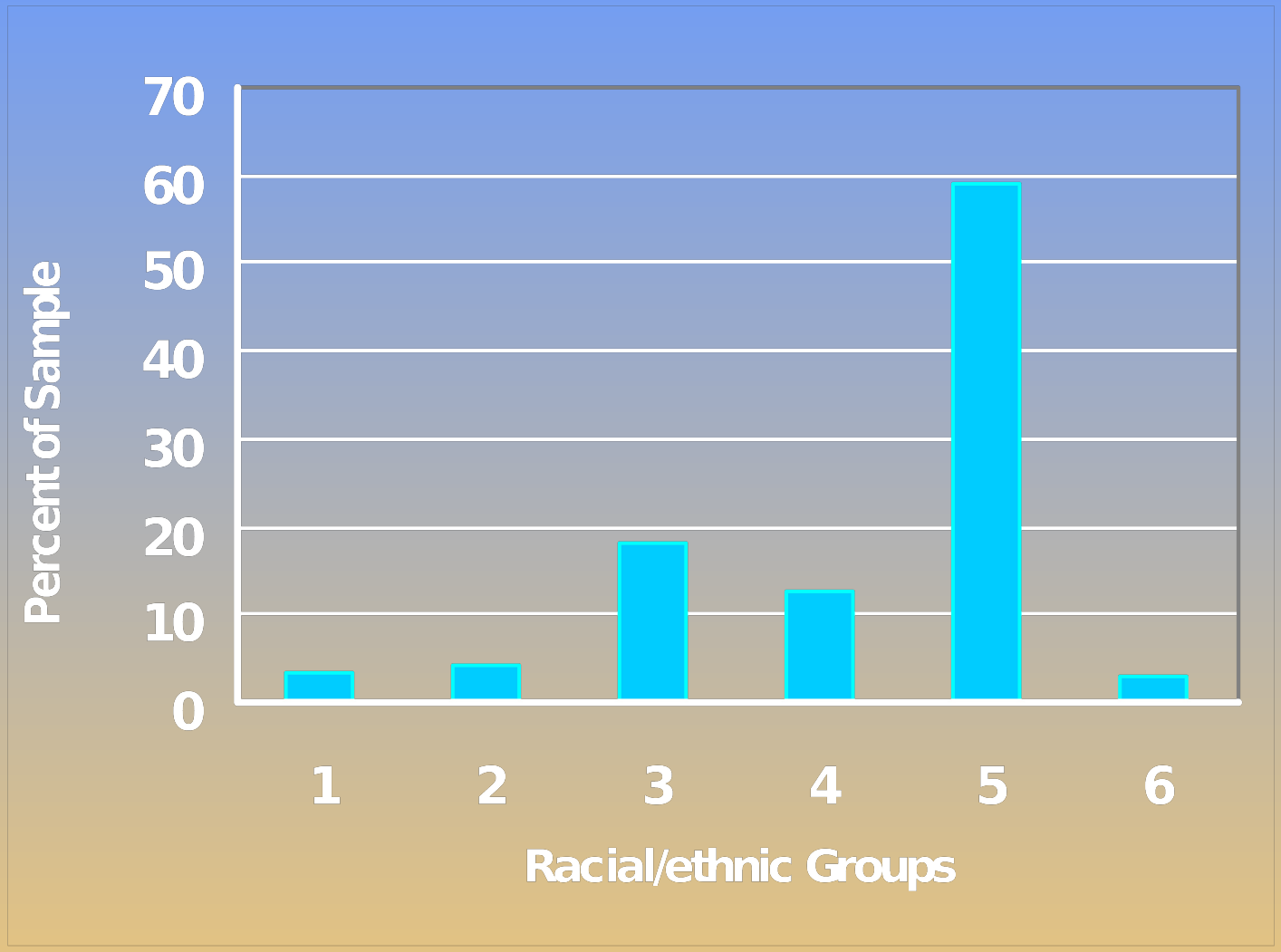
Anticipated completion of data collection in December 2005

Enrollment Numbers

- Enrolled 4647
- Discharged from Navy 355
- Withdrew from study 1001
- Completed 2803

- Study retention has been 60 – 79%

Racial/Ethnic Breakdown of Sample



1- Am. Indian
2- Asian
3- Black
4- Hispanic
5- White
6- Other

Description of Sample

Variable	Mean ± SD
•Age (yrs)	20.2 ± 2.7
•Age at menarche	12.5 ± 1.5

Questions